

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

#4  
JRP  
11/19/03Inventors George Kindness : Group Art Unit: 1614  
Brooke Schumm III  
F. Timothy Guilford

Appl. No. 09/997,490 : Examiner: Jerome D. Goldberg

Filed: November 17, 2001

For: A COMBINATION AND METHOD OF TREATMENT OF CANCER  
UTILIZING A COX-2 INHIBITOR AND A 3-HYDROXY-3-METHYLGLUTARYL-  
COENZYME-A (HMG-CoA) REDUCTASE INHIBITORCONTINUATION IN PART OF PROVISIONAL APPLICATION 60/245,592 FILED  
November 17, 2000, AND PROVISIONAL APPLICATION 60/264,511 filed January 26, 2001,  
and PROVISIONAL APPLICATION 60/307,689 filed July 25,2001To: Assistant Commissioner of Patents  
Alexandria, VA 22313-1450ELECTION OF CLAIMS

Applicants make election to the invention(s) proposing the composition of a glutathione pathway enhancing and detoxifying compound, in particular cystine, combined with a selective COX-2 inhibitor and a statin. This includes claims 2, and 3, and 4, 5 and 6. Further included are claims 11,12, and 13 which are multiply dependent on claims 1-10, but election here would be to those claims only as they depend on claims 2-6. Based on the examiner's comments in the telephone interview, election as set forth in the first paragraph appeared acceptable.

The examiner is authorized to make the amendment by interlineation. Such interlineation is striking the characters "--1-10--" in claim 11 and inserting in their place "--2-6--", striking the

characters "--1-10--" in claim 12 and inserting in their place "--2-6--", and striking the characters "--1-10--" in claim 13 and inserting in their place "--2-6--". Alternatively, if a preliminary amendment is needed on claims 11,12, or 13, Applicants will submit one shortly.

Applicants submit that statins are generally looked upon as a group of similarly acting compounds: that is 3-HMG CoA Reductase Inhibitors.

Applicants submit that selective COX-2 inhibitors are also generally looked upon as a group of similarly acting compounds with selective inhibition of the COX-2 biochemical pathway in preference to the inhibition of the COX-1 biochemical pathway.

A reference that cites the latter statins as a group and generally interchangeable within that group, and selective COX-2 inhibitors as a group and generally interchangeable within that group is, "Goodman & Gilman's The Pharmacologic Basis of Therapeutics (9th ed. McGraw-Hill 1996).

A substantial number of other patents have been allowed citing classes of statins and selective COX-2 inhibitors including Winokur, 6,245,797, June 12, 2001.

If the examiner does not believe that the class grouping is reasonable as done in pharmaceutical guides, election with traverse is made on use of statins and selective COX-2 inhibitors as a group. If the examiner requires a single compound of the class of statins and a single compound of the class of selective COX-2 inhibitors be selected, then applicants would

elect celecoxib and atorvastatin. Again, based on the examiner's comments, election as set forth in the first paragraph appeared acceptable.

Examiner Goldberg is respectfully thanked for his suggestions and wished a successful retirement.

Date: 9/26/2003

Respectfully submitted,

Brooke Schumm

Brooke Schumm III

Pat. Atty. #34,926

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on behalf of Applicants

#### CERTIFICATE OF SERVICE

I certify I caused a copy of the above Election to be telecopied by facsimile machine to (703) 872-9306 on this 26<sup>th</sup> day of September, 2003, to the Assistant Commissioner of Patents, Examiner Goldberg, Group Art Unit 1614, Washington DC 20231

Brooke Schumm

Brooke Schumm III

Date 9/26/2003

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*Brooke Schumm III* 84,928

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